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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,322	12/20/2001	Maria Gabriella Santoro	10167-013-999	9500

7590

03/29/2005

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New York, NY 10036-2711

EXAMINER
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WILLIAMS, LEONARD M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/937,322

Applicant(s)

SANTORO ET AL.

Examiner

Leonard M. Williams

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 37-78 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The preliminary amendment received 09/21/2001 canceling claims 1-36 and adding new claims 37-78 is acknowledged and entered. Claims 37-78 are to be considered on their merits.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 37-73, drawn to a method for treating or preventing a disorder in a host.

Group II, claim(s) 74-78, drawn to a method for treating or preventing a disorder in a plant.

### ***Species Election***

This application contains claims directed to more than one species of the generic inventions. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group I is elected then a compound species election and a disorder species election is required.

If group II is chosen a compound species election is required and a disorder species election is required.

The species are as follows:

**Compound Species Election:**

1) One compound specified by selection of one specific substituent embodiment for each of  $R_{1-9}$  and X for either formula (a) or formula (b) of claim 37.

2) One compound specified by selection of one specific substituent embodiment for each of  $R_{1-9}$  and X for either formula (a) or formula (b) of claim 38.

3) One compound specified by selection of one specific substituent embodiment for each of R,  $R_{1-2}$ , X and Y for either formula (i), formula (ii), formula (iii) or formula (iv) of claim 39.

4) R-(+)-4-tert-butyldimethylsilyloxy-cyclopent-2-en-1-one of claim 41.

5) S-(-)-4-tert-butyldimethylsilyloxy-cyclopent-2-en-1-one of claim 42.

6) One compound specified by selection of one specific substituent embodiment for each of R,  $R_{1-2}$ , X and Y for either formula (i), formula (ii), formula (iii) or formula (iv) of claim 76.

7) R-(+)-4-tert-butyldimethylsilyloxy-cyclopent-2-en-1-one or S-(-)-4-tert-butyldimethylsilyloxy-cyclopent-2-en-1-one of claim 77.

**Disorder Species Election:**

1) Disorder associated with NF-kB of claim 56.-

2) Viral-mediated disorder of claim 57.

3) Bacterial-mediated disorder of claim 59.

- 4) Disorder resulting from radiation of claim 60.
- 5) Inflammatory disorder of claim 61.
- 6) Disorder of the immune system of claim 62.
- 7) Ischemia of claim 63.
- 8) Arteriosclerosis of claim 64.
- 9) Cancer of claim 66.
- 10) Disorder involving damage to or killing of cells of claim 67.
- 12) Diabetes of claim 68.
- 13) Disorder involving calcium loss or deficiency of claim 69.
- 14) Disorder is a viral disorder of claim 78.

Applicant is required, in reply to this action, to elect a single species of compound and a single species of disorder to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Compound Species:

- 1) One compound specified by selection of one specific substituent embodiment for each of  $R_{1-9}$  and X for either formula (a) or formula (b) of claim 37.
- 2) One compound specified by selection of one specific substituent embodiment for each of  $R_{1-9}$  and X for either formula (a) or formula (b) of claim 38.
- 3) One compound specified by selection of one specific substituent embodiment for each of R,  $R_{1-2}$ , X and Y for either formula (i), formula (ii), formula (iii) or formula (iv) of claim 39.
- 4) R-(+)-4-tert-butyl dimethylsilyloxy-cyclopent-2-en-1-one of claim 41.
- 5) S-(-)-4-tert-butyl dimethylsilyloxy-cyclopent-2-en-1-one of claim 42.

Disorder Species:

- 1) Disorder associated with NF-kB of claim 56.
- 2) Viral-mediated disorder of claim 57.
- 3) Bacterial-mediated disorder of claim 59.
- 4) Disorder resulting from radiation of claim 60.
- 5) Inflammatory disorder of claim 61.
- 6) Disorder of the immune system of claim 62.
- 7) Ischemia of claim 63.
- 8) Arteriosclerosis of claim 64.
- 9) Cancer of claim 66.
- 10) Disorder involving damage to or killing of cells of claim 67.

12) Diabetes of claim 68.

13) Disorder involving calcium loss or deficiency of claim 69.

The following claim(s) are generic: 37-39, 44-51, 65, and 74-77.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature is a compound containing a cyclopentenone core structure. Cyclopentenone containing compounds are well known in the art and include such compounds as prostaglandins (and their derivatives), specific cyclopentenone compounds known in the art can be found in US Patent 5352708, US Patent 6548543 and US Patent No. 5329035.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW



**GREENI PADMANABHAN**  
SUPERVISORY PATENT EXAMINER